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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/921,922 | 08/06/2001 | Linda Trolinder | 58764.000033 | 8576 |

7590

01/16/2004

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 09/921,922 | Applicant(s) TROLINDER ET AL. | |
| | Examiner David H Kruse | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 20-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4,5 and 20-22 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 23-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>05/03</u> | 6) <input type="checkbox"/> Other: |

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed 7 November 2003.
2. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
3. Applicant's statement regarding deposit of biological materials has been reviewed and is deemed sufficient. The rejection under 35 USC § 112, first paragraph, for enablement as directed to the deposit of biological material has been overcome.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. The information disclosure statement filed 28 May 2003 has been considered, a signed copy is attached hereto. Applicant should note that reference #6 has been crossed-out, it has been considered but is not a proper, publicly available reference to be published on the face of the patent.

Claim Rejections - 35 USC § 112

6. Claims 1-3 and 23-26 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 7 May 2003. Applicant's arguments filed 7 November 2003 have been fully considered but they are not persuasive.

As directed to claims 1-3, Applicant argues that elite event EE-GH1 can be introduced into any and all cotton plants or cultivars by classical breeding techniques, such as recurrent backcrossing (page 6, 4th paragraph of the Remarks). This argument is not found to be persuasive because the instant claims are not directed to a product by process wherein said product is produced from the deposited line PTA-3343, but reads on reproducing the elite event EE-GH1, which the Examiner maintains is unpredictable and would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention without the PTA-3343 deposit line.

As directed to claims 23-26, Applicant argues that all that is required by these claims is that the transgene is inserted into the insertion site where the transgene is inserted in elite event EE-GH1 and that the fact that the art allegedly teaches that homologous recombination in cotton plants is irreproducible is irrelevant. Applicant argues that having at hand the complete nucleotide sequence of the insertion region that it is well within the capacity of a person skilled in the art to screen those plant cells or plants where the insertion of the transgene has occurred to the indicated region recited in those claims (pages 7-8 of the Remarks). This argument is not found to be persuasive because it is pursuant upon Applicant to teach one of skill in the art how to make and use the invention. Simply screening through random insertion events to identify those with transgenes in the identical region that elite event EE-GH1 occurs would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention. In addition, the Examiner reiterates that homologous recombination in plants, at the time of Applicant's invention, was highly unpredictable

and hence the products of claims 23 and 26, and the process of claims 24 and 25 would have required undue trial and error experimentation given the guidance by Applicant and the state of the art at the time of Applicant's invention.

Conclusion

7. Claims 4, 5 and 20-22 are allowed.
8. Claims 1-3 and 23-26 remain rejected.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, appearing to read "Amy Nelson".

David H. Kruse, Ph.D.
2 January 2004

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600